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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,933	02/27/2002	Peter Sondermann	HUBR-1189(10	7771

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,933	SONDERMANN ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *41-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 05/30/01 is acknowledged.

Claims 41- 80 are pending.

Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

For examination purposes, "use" claims 57,58,64-68,75,76 and 79-80 are prosecuted as "methods of use" claims.

I -VI. Claims 41-45 , 59-61 and 77-78 are drawn to one specific recombinant soluble Fc receptor having no transmarine domains and no signal peptide and wherein no glycosylation occurs, wherein said receptor contains one specific amino acid sequence of SEQ ID NOs. 1-6 , a pharmaceutical composition containing one said soluble Fc receptor and one said Fc receptor bound to a solid phase .

VII-XII. Claims 46-49 are drawn to one specific recombinant nucleic acid containing one specific sequences of SEQ ID NOs: 7-12 and a host cell characterized by the presence of the said one specific recombinant nucleic acid.

XIII Claims 50-53 are drawn to a process for the determination of the amount of antibodies of a certain Ig class in the blood, plasma or serum of a patient , comprising the use of recombinant soluble Fc receptor having no transmarine domains and no signal peptide and wherein no glycosylation occurs , wherein the antibodies are IgE and recombinant soluble Fc receptor is a FcγR.

XIV Claims 50, 51 and 54 are drawn to a process for the determination of the amount of antibodies of a certain Ig class in the blood, plasma or serum of a patient , comprising the use of recombinant soluble Fc receptor having no transmarine domains and no signal peptide and wherein no glycosylation occurs , wherein the antibodies are IgG and recombinant soluble Fc receptor is a FcεR.

XV. Claims 55-56 are drawn to process for determination of the immune status of patients with chronic diseases of the immune system using a recombinant soluble Fc receptor having no transmarine domains and no signal peptide and wherein no glycosylation occurs.

XVI. Claims 57-58 are drawn to a method of using a recombinant soluble Fc receptor for the screening of the substances for their ability to act as inhibitors of the recognition and binding of antibodies to cellular receptors.

XVII. Claim 62 is drawn to a crystalline preparation of a soluble recombinant Fc receptor.

XVIII. Claim 63 is drawn to a crystalline preparation of a complex of soluble recombinant Fc receptor/immunoglobulin.

XIX. Claim 64 is drawn to a method of using a crystalline preparation of a soluble recombinant Fc receptor for generation of crystal structure data of Fc receptor.

XX. Claim 65 is drawn is to a method of using a crystalline preparation of a complex of soluble recombinant Fc receptor/immunoglobulin for generation of crystal structure data of receptor/Ig complexes and their respective binding sites.

XXI. Claim 66 is drawn to a method of using crystal structure data of Fc receptor for identification and/or preparation of Fc receptor or immunoglobulin inhibitors.

XXII. Claim 67 is drawn to a method of using a crystal structure data of a complex of soluble recombinant Fc receptor/immunoglobulin for identification and preparation of new antibody receptors.

XXIII. Claim 68 is drawn to a method of using crystal structure data of Fc receptorin a computer-aided modeling program.

XXIV. Claims 69, 71 and 73-74 are drawn to an RcR inhibitor which is complementary to the recombinant soluble FcR and a pharmaceutical composition containing said FcR inhibitor.

XXV. Claims 70 and 72 are drawn to an immunoglobulin inhibitor and a pharmaceutical composition containing said inhibitor.

XXVI. Claims 75 and 76 are drawn to a method of using of a molecule for modulation of the interaction between an Fc receptor and immunoglobulin.

XXVII. Claims 79 and 80 are drawn to a method of using a chromatography carrier material, wherein a recombinant soluble Fc receptor having no transmarine domains and no signal peptide and wherein no glycosylation occurs bound to a chromatography carrier material for adsorption or enrichment of antibodies from a patient's blood, serum or plasma or from culture supernatant of immunoglobulin producing cells.

3. The inventions listed as Groups I-XXVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of EP-A 0614979 and Depsited amino acid sequence of FcγR1 assertions NO: P12314

EP'979 teaches a recombinant soluble FcγR receptor that lacks the transmembrane domain, is not glycosylated and does not have a signal peptide and a pharmaceutical composition comprising said receptor. The deposited amino acid sequence of FcγR1 assertions NO: P12314 is 100% identical to claimed SEQ ID NO:1

Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to Rubin D on 3/26/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 5, 2004

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